

In re Application of: Elan ZIV
Serial No.: 10/598,872
Filed: May 18, 2007
Office Action Mailing Date: October 12, 2010

Examiner: Catherine E. BURK
Group Art Unit: 3735
Attorney Docket: **34061**
Confirmation No.: 1651

REMARKS

The application contains claims 1-13, 15, 16, 18-22, 26-29, and 32-37. Claims 1, 26 and 35 are amended. Claim 14 has been canceled. Claims 23-25 and 30-31 have been withdrawn in response to the Restriction Requirement dated August 4, 2010.

Claim Rejections under 35 U.S.C. §112, second paragraph

Claim 35 has been amended to change redact the words “said sizes of” which lacked proper antecedent basis.

Claim Rejections under 35 U.S.C. §102(b)

The Examiner has rejected claims 1-11, 13, 14, 16, 18-22, 26-29, 32, and 34-37 under 35 U.S.C. §102(b) in view of US 5,785,640 to *Kresch* (“the ‘640 patent”). Applicant respectfully disagrees with this rejection for the reasons set forth below.

First, not all of the limitations of independent claims 1 and 26 are taught by the ‘640 patent. Claims 1 and 26 recite the limitation that the support section is “adapted for providing urethral support”. However, the device of the ‘640 patent is NOT adapted to provide urethral support but instead to provide bladder neck support. *See* FIG. 5 (where support member 6 and 8 are shown supporting the bladder neck and not the urethra) and Col. 5, lines 4-15 (where it is stated that the bladder neck is supported and that the support members are specially sized and shaped to render bladder neck support), *inter alia*.

Second, the amendment to claim 1 incorporating claim 14 and clarifying that the apparatus of claim 1 is rotationally symmetrical around the central axis further distinguishes the claimed device over the ‘640 patent. Support for this amendment can be found in original claim 14, as well as FIGS. 1B, 2B, 2C, 4B, 6B, 6C, *inter alia*, and the descriptions pertaining thereto in the specification.

It should be understood by the Examiner the value of having a rotationally symmetrically arranged device for insertion into the vagina, that is, that the device can

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be inserted without regard to rotational orientation about the central axis and still render effective incontinence treatment.

In contrast, it can be seen that the '640 patent describes a device which is not rotationally symmetrical about its central axis, see for example FIGS. 4A and 4B. Clearly, there is a side which is adapted for rendering support to the bladder neck and a side opposite which is adapted for supporting the device within the vagina using the vaginal floor. In addition to there being a distinctive "top" and "bottom", insertion of the '640 patent device sideways would be ineffective for rendering treatment and likely extremely uncomfortable.

The rotationally symmetrical arrangement of the present invention results in a far more usable incontinence treatment device than the device described in the '640 patent, which practically speaking also favorably affects patient compliance.

In view of these arguments, claims 1-11, 13, 16, 18-22, 26-29, 32, and 34-37 are novel in view of the '640 patent.

Claim Rejections under 35 U.S.C. §102(b)

The Examiner has rejected claims 1, 4, 12 and 13 under 35 U.S.C. §102(b) in view of WO 2000/067662 to *Huseth, et al.*, marked as *Gluck* by the Examiner, ("the '662 publication"). Applicant respectfully disagrees with this rejection for the reasons set forth below.

As discussed above, claim 1 has been amended to include the limitation that the device is rotationally symmetrically arranged around the central axis.

The devices described in the '662 publication are not rotationally symmetrically arranged around their central axes. Rather, they have one support providing member on the side facing the urethra and at least two anchoring providing members opposite the urethra and pointing towards the vaginal floor. See FIGS. 8, 11 and 12. Because of the asymmetrical arrangement of the '662 publication devices, a woman has to take special care upon insertion of the devices that they are positioned correctly and that the support providing member (34, 44) is facing towards her urethra.

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Because not all of the limitations of independent claim 1 are taught by the '662 publication, claims 1, 4, 12 and 13 are novel.

Claim Rejection under 35 U.S.C. §103(a)

The Examiner has rejected claim 15 under 35 U.S.C. §103(a) as being obvious in view of the '640 patent. Applicant respectfully disagrees with this rejection for the reasons set forth below.

The '640 patent, even in combination with the knowledge of one with ordinary skill in the relevant art, does not teach all of the limitations of rejected claim 15. As described above, claim 1 includes the limitations of urethral support and being rotationally symmetric, neither of which are described in the '640 patent.

Applicant believes that at least for this reason, claim 15 is non-obvious in view of the '640 patent.

Prior to mailing of the Examiner's next Official Action, the Examiner and his Supervisor are invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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